FDA 510(k) Premarket Notification

CLEARED

K200811 cobas u 701 microscopy analyzer

Nov 6, 2020
224 days to decision

K200811 · Product code: **LKM** · Hematology
Source: https://www.510kdatabase.net/k200811/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Urine Particle (LKM)
Date received	Mar 27, 2020
Decision date	Nov 6, 2020
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Roche Diagnostics**
Location	Indianapolis, IN, US
Contact	Teresa Carrow
Website	https://diagnostics.roche.com
510(k) history	182 submissions · 180 cleared · 2005-2026

Roche Diagnostics is a Swiss multinational healthcare company specializing in diagnostic devices and solutions. The company operates its U.S. diagnostics division from Indianapolis. Roche Diagnostics maintains a strong FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 2005. The company's portfolio spans chemistry devices, immunology assays, microbiology testing, and hematology systems. The latest clearance in 2026 reflects continued innovation and regulatory engagement. Recent cleared devices include glucose monitoring systems, elec...